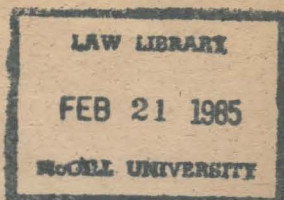


Vol. V No. 19



Thursday, February 21, 1985

Quid Novi

A McGill Faculty of Law Students' Publication
AND



the Tablet

A McGill Faculty of Medicine Students' Publication

A SPECIAL JOINT ISSUE

PHARMACEUTICALS

AND THE

LEGAL

Insights



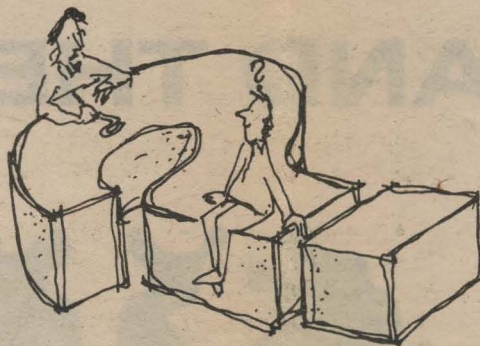
Introduction

by Debra Raicek
Faculty of Law

It can be said that both the Law and Medicine are two rather introspective professions. Although ideally one exists to ensure the pursuit of justice and the other to reduce the suffering of mankind, the scope of these noble aims tends to narrow in their everyday performance. Perhaps the most interesting and rewarding part of working on this publication was the insight which we, students of both the Faculties of Law and Medicine, were able to glean from each other's motivations, aspirations and views of the world at large.

This issue covers a diverse range of controversial topics. The role of ethics committees, the right to be a parent, the escalation of malpractice suits, the right to die, new technology in fertilization and liability in the pharmaceutical industry present questions which hold no hard and fast answers.

The problems we face today seem to have altered fundamentally from the teachings of Plato and Hippocrates, yet our aims are the same; to do what is just and to cure the sick. It is only by broadening our views and working together that we can bring the ideals of the past into a technologically burgeoning future. Society as a whole is facing a new era of technological advancement and with it the age-old professions of Law and Medicine are facing a new horizon of challenges and decisions. The answers lie not in a conflict between that which is medically feasible and that which is legally permissible, but rather through a shared effort to work towards solutions which are medically, legally and



This issue was conceived and produced by Debra Raicek and Pearl Eliadis.

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Revival of an Old Liaison: Educating for Modern Health Law Issues

by Margaret A. Somerville
Professor, Faculty of Law
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Two common perceptions of health law are, first, that it is a very recent phenomenon and, second, that those involved in the area spend most of their time dealing with medical malpractice and, hence, that the field encompasses, principally, disagreeable confrontations between physicians and lawyers. Both of these perceptions are in error.

While it is true that there is an unprecedented current popularity of health law and related bioethical issues in the media, the field has a long history. Academic curricula including these topics date back at least to the eighteenth century in Europe. Second year law students at McGill faced a compulsory examination in Medical Jurisprudence in 1873. And, not only was medical jurisprudence taught at McGill Medical School in the nineteenth century, but there were professors of medical jurisprudence. Moreover, in most medical school the teaching of psychiatry was first introduced as part of medical jurisprudence at the beginning of the twentieth century. Consequently, it may be more accurate to refer to a current revival of interest in this field, rather than to undertake exploration of entirely new territory.

This revival has been caused by a concurrence of factors which include the extraordinary advances of modern biomedical technology and a better educated, media oriented public, which is hungry for news of modern "medical miracles"; possibly to some degree because medicine has taken over roles or functions previously filled by religion. Thus, not only is it important



for physicians, lawyers and, therefore, for medical and law students, to address these critical issues, but to avoid doing so has become virtually impossible.

A related question concerns the increased involvement of the law in the every day practice of medicine. The reasons for this include the nature of the decisions that must be made by medical professionals. The most striking of these is "triage" — deciding who will live and who will die, a decision which is rarely dealt with directly developed Western societies. Secondly, health care has become "Big Business", and thirdly, "Big Government" is involved. Any one of these factors would make it likely that there would be direct involvement of the law, the presence of all of them makes this inevitable.

In the academic context, health law is fruitful ground for transdisciplinary research into matters ranging from the mental health of an individual, to the legal health of a society. But, perhaps, most importantly, for present students, high

profile health law and bioethical issues are transformed into questions regarding what should be the impact of modern health law and bioethics on legal and medical education. This is a topic under consideration at McGill, as it is at almost all North American universities which have schools of law and of medicine. A survey project sponsored by the American Society of Law and Medicine in Boston has been conducted over the past two to three years and a report is presently being drafted.

Among the matters that the ASLM Task Force has considered, is the definition of "health law". This has proven to be difficult to articulate. "Health law", as a discrete concept, requires a broad definition that would include all relevant concerns, exclude irrelevant ones and assist in establishing decision-making structures. Because of the universal character of medicine, ideally, any definition of health law would be applicable in any legal jurisdiction, and any legal framework established pursuant

to this definition, would have to be both flexible and usable as a problem-solving tool.

Optimally, health law education would merge not only legal and medical disciplines, but would also include elements of, and ready access to, the disciplines of ethics, economics, theology, sociology, and anthropology. It is extremely important that education in this field be transdisciplinary, if it is to give medical and law students an opportunity to develop new attitudes both to the problems they address and to working with each other. Law students could benefit immeasurably through a carefully structured learning experience in a medical school. Such exposure could assist law students to better appreciate the emotionally charged and difficult decisions that must be made on a daily basis in the health care milieu. There has already been some limited experiments in this regard at McGill. For instance, this year some senior law students have been working with a hospital-based, gerontology unit. The opportunities for this type of

experience will become more important for law students, if the United States trend of appointing in-house legal counsel in major hospitals, is adopted in Canada. Although many physicians may be horrified at the thought of having lawyers working in a hospital, most hospitals which have implemented such a scheme, have found that physicians find it helpful, both for immediate problem-solving, when legal and ethical issues are involved, and from a continuing professional education viewpoint.

For all students, health law provides an opportunity to learn to deal with uncertainty in decision-making. It also provides occasions for students to develop both their own values and respect for those of other persons, and of learning how to factor into decision-making, principles of uncertain or changing content, such as concepts of public policy. Because health law is heavily value-oriented, careful attention should be paid to the attitudes and values inherent in health law and in teaching it.

Finally, there is an increasing awareness on the part of both our Faculties of Medicine and of Law that they should take advantage of the opportunity that is available in health law education, to create a cooperative and meaningful interchange between health and law professionals. In this respect, McGill offers various courses involving medicine and law, including a concentration in health law area in graduate law studies leading to a masters or doctoral degree. It is to be hoped that such educational efforts rebound to the benefit of those whom both professions seek to help and to the future professionals, themselves, in the practice of their professions.

On the Frontier



with Michael Ruckstein
Faculty of Medicine

At the recent International Congress on Child Abuse in Montreal, Dr. David Roy suggested that prospective parents should be required to obtain official sanction in order to have children. Head of the Montreal Clinical Research Institute's Center for Bioethics, Roy has been searching for ways to reduce the incidence of abuse and neglect. His idea of refusing couples the right to have children pending proof of social and moral responsibility is still in its nascent stages. The Congress provided Roy with his first opportunity to present his thoughts formally and to receive feedback from over two thousand doctors, social

workers and psychologists in attendance.

"It is an ethical dilemma," he said, "We don't want a police state poking its nose into our bedrooms. At the moment I don't know how to solve this problem (child abuse) and I doubt if anyone does."

"We all make pious statements that children are our highest priority and our greatest natural resource, and we know that parenthood is the most important role in society, but we let it happen naturally, and we can't let it happen naturally, and we can't do that any more."

Roy went on to explain that "we have no adequate profile of potentially abusive parents and even if we did, how can we ensure that such criteria would not be manipulated, for example, to the detriment of some ethnic group?" Furthermore, he suggested that the development of sterilization methods would provide the technical means

necessary for the application of his theory. With such a contraceptive, procreative abilities could be turned off at puberty and turned on again when the individual is proven to be an able parent.

At the same conference, Ann Cohn, Director of the National Committee for the Prevention of Child Abuse in the United States, suggested some less radical methods of controlling child abuse and neglect. She explained that government cannot be expected to stamp out child abuse. "Laws won't help child abuse," she said, "Government resources are tied up with investigative, medical and protective service costs after abuse has occurred."

Cohn advocated that corporations, community groups should band together to stamp out child abuse. She added that in the United States over \$2

The Role of Clinical Ethicists

by Frank Vona
Faculty of Medicine

"Into whatever houses I enter, I will go into them for the benefit of the sick"

From the time of the induction of the first apprentice into the Order of Physicians to the present where we graduate hundreds of medical students at a time, this oath and the ideal contained in it have served as the sole required ethic for physicians. But reciting these lines does not qualify them to uphold this ethic. Nor does it guarantee that they will have even considered the charge of the oath and its supposed impact on medical decisions. Yet the ethic has rarely been questioned. Is this due to a belief that the great investment made in medical training belies a conviction to do only what is right? Surely the wisdom of physicians must grow with each case that is treated — successfully or otherwise — thereby increasing our faith in their decisions. This may have been so in the past.

Today, however, many are questioning the judgement of physicians and this is already changing the practice of

medicine. Defensive medicine is now more common in our hospitals; more diagnostic tests are ordered so that nothing will be missed; the second opinion is a standard request today, and society has increased its interest in medical ethics to the point where many hospitals have begun to establish medical ethics committees. Although this trend is widespread in North America, it is not receiving the full support of physicians. A number of arguments bolster this position. Before examining them, the structure and function of these committees should be described.

The structure of the ethics committee varies from one institution to another. It may consist of physicians, nurses, clergymen, professional ethicists and so on. Presently their functions are ill-defined, but three major ones are common to most of them: 1. Determining hospital policy (eg. Do-Not-Resuscitate-Orders); 2. Assisting physicians in ethically difficult cases; 3. Educating physicians in the study of ethics.

1. Established guidelines forming hospital policy perform

two functions. They protect the hospital against legal action by ensuring that experts have considered such cases in depth. Guidelines also serve to unify the actions of physicians in a given hospital. Three problems may arise. First, as the final decision in a case rests with the physician, the responsibility for the consequences of following a particular course of action also rests with that physician. If hospital guidelines are contravened, the physician may be liable to both the hospital and the patient if something goes wrong. A physician's independence is obviously hindered. Second, the guidelines will certainly become more detailed and specific as these committees become more established. Could the policies eventually become so specific as to lower the physician to the role of technicians who simply dispense medicines and carry out procedures to the specifications of a complex set of hospital rules? Third, in establishing hospital policy, these committees cannot claim success in terms of *establishing* moral precedents where legisla-

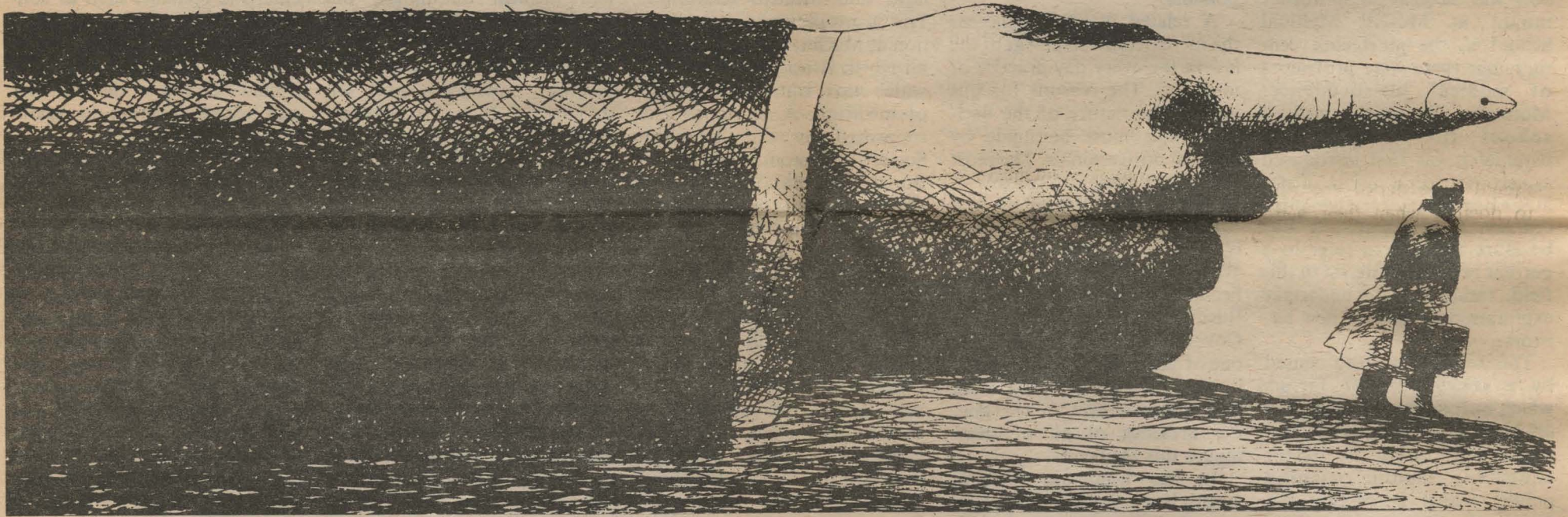
tion already exists. If national policy (legislation) states that withholding treatment is a criminal act, then no local policy will make it lawful. That is, a committee cannot produce a policy that is not already acceptable to society — and to physicians.

2. In hospitals where such committees exist, the physician is encouraged to consult with them whenever an ethically difficult choice is required. The question arises as to whether the committee is more qualified than physicians or even laymen to evaluate ethical alternatives. Does education in ethical analysis furnish the wisdom to make moral value judgements? Is experience in patient care a more valuable parameter?

3. The ethics committee as a teaching body has a long way to go. At the undergraduate level, a solid basis in background theory must be given so that during clinical years applications of the theory will be obvious. Ethical grounds can serve as a thought provoking stimulus for continuing medical education. They may also serve as a forum providing up to date in-

formation in major legal decisions in medico-moral cases. As in any medical specialty, however, the value of a sensitive role model as teacher cannot be overstated. Who will fill this role in the hospital? The ethicist or the clinician?

For as long as physicians have existed as respected figures in society, they have been aware of the morality of the decisions which are taken. Because they live with such decisions daily and because the responsibility for their consequences rests solely on the medical profession, they should maintain their positions as moral agents. Medical decisions should not rely only on the beliefs of the most vocal group. Care must be taken to distinguish between moral rights and legal rights, and the two should never be confused. Finally, it is true that moral rights can only become legal rights at the legislative or judicial levels, then the ethics committee would best fulfill its mandate at those levels and not in the hospital in order to advise on ethically difficult scenarios.



Pulling the Plug Withdrawal of Care and the Incompetent Patient

by Robert Metcalfe
Faculty of Law

In testimony before the Supreme Court of New Jersey in the Karen Quinlan case, a medical expert noted that early life support technology was inherently limited by the inability to supply patients with adequate nutrition. High-caloric tube feeding has overcome this problem, and it is now possible to keep comatose patients almost indefinitely suspended between life and death. While this facilitates the preservation and retrieval of organs for transplantation, the legal and ethical dilemma created by this new state of biological purgatory is acute. In *Leach v. Akron General Medical Center* an American court raised the following concerns:

Since man, through his ingenuity, has created a new state of human existence — minimal human life sustained by man made life supports — he must now devise and fashion rules and parameters for that existence.

Who, then, should we trust with the ultimate jurisdiction of creating and enforcing these rules, and what procedural safeguards exist to prevent their abuse? In medical law, the starting point of all discussion of appropriate courses of treatment in recent years has been the doctrine of informed consent, the patient's right to an autonomous decision based on full disclosure of all information necessary to an informed choice. But with incompetent patients, where by definition the patient's wishes cannot be ascertained directly, the con-

siderations are different. In theory at least the doctrine of informed choice has been preserved in the case of incompetent patient's through the notion of a guardian's consent to treatment, but there has been much discussion as to the duty of treatment in cases of critical illness and the appropriate forum for determining the patient's best interests. Often the dispute between the medical and the legal professions has obscured rather than clarified the duty to treat and the appropriate decision making procedures.

The history of the Harvard Brain Death Test provides an interesting illustration. Designed in 1968 to provide a new definition of death and to facilitate the retrieval of donor

organs for transplantation, the test identified four symptoms of irreversible coma: no response to externally applied stimuli; no movement or breathing; no reflexes; and a flat electroencephalogram. Once these conditions are met, a patient may be declared dead and any life support system withdrawn. The sequence here is important, as the group formulating the rule felt that it provided a degree of legal protection to the medical staff involved. Should death not be declared first, "the physicians would be turning off the respirator on a person who is, under the present strict, technical application of the law, still alive."

Certainly a new medical and legal definition of death was required, and this proposal has been adopted legislatively in many states, used by courts in others, and applied widely by physicians in a clinical context. More recent medical studies have suggested that the test is defective in several ways, particularly in that reflex activity can be observed in case of brain stem failure. Furthermore, it soon became apparent that the Harvard test did not provide

easy answers to many lingering questions concerning treatment in marginal cases. A British medical journal pointed out the limits of the test when it published a report of a chicken which had been the victim of an unsuccessful decapitation. The front part of the skull and brain had been removed, leaving the brain stem intact. Fed with an eyedropper, the bird remained alive for six days. Transposed to a human context, this case raises the question whether there should be an obligation to treat a patient who, though not brain dead, stands little chance of recovery. A general response to this question is difficult if not impossible to formulate, but an unrestricted positive answer is subject to both medical and legal abuse. In one such case, a lawyer for an arsonist applied for an injunction to restrain a hospital from withdrawing treatment from a badly burned infant who was not brain dead, hoping that by doing so he could forestall a murder charge against his client.

These are some of the more grotesque examples of the limits of the Harvard test, but a misunderstanding of its purpose

and function has created problems even in the most conventional areas of application. In many instances, an excess of caution engendered by a not unreasonable fear of litigation has led many hospitals to confuse what was meant to be a definition of death with an obligation to treat. In the *Quinlan* case all parties agreed that the patient's chances of recovery were minimal, but the attending physicians repeatedly refused to turn off the respirator as requested by the family. The hospital argued that she was not clinically dead according to the brain death test, that they therefore had a duty to treat her, and that they could be exposed to criminal or civil liability should treatment be withdrawn.

In the *Quinlan* case the father ultimately petitioned the court to be named the patient's guardian and to be granted the express power to authorize the life support machinery to be disconnected. This request was denied at trial. The presiding judge affirmed the hospital's contention that the controlling decision belonged to the physician rather than the patient, the guardian or the courts:

The nature, extent and duration of care by societal standards is the responsibility of the physician. The morality and conscience of our society places this responsibility in the hands of the physician. What justification is there to remove it from the control of the medical profession and place it in the hands of the courts.

It is surely questionable whether this controlling power should be assigned exclusively to doctors when their actions may be governed by self-interest. An appeal to a higher court reversed the trial decision and approved the application. The Court held that there is a constitutional right of privacy which permits a patient to refuse treatment, and that the right can be exercised by the guardian of an incompetent patient acting in the patient's "best interests". This right to resist treatment is qualified, however, by the competing interest the state has in preserving life. The state's interest might override the patient's right of refusal, as in the case of a Jehovah's Witness who refuses a life-saving blood transfusion for a minor child, but the Court allowed that the patient's right to resist treatment should prevail over competing interests where there is no genuine hope of recovery.

The higher court's judgement in *Quinlan* is instructive in several respects. First, it asserts that the patient does have a right to refuse treatment and that this right must be balanced against other countervailing interests, notably the state's concern for the preservation of life and the physician's right to treat as he or she sees fit. Second, in inquiring whether treatment may be withdrawn the focus should be on the "prognosis as to the reasonable possibility of a return to cognitive and sapient life" rather than on the stricter Harvard Brain Death Test. Third, the courts have a role in balancing the respective interests and can review what was formerly considered to be a purely medical decision. However, the treatment should normally be made within the

patient-doctor-family relationship and need not be subjected to routine judicial scrutiny. In this respect the judge nodded approvingly at the lower court's finding and prescribed a procedure which would allow such decisions to be made in the future without the necessity of "gratuitous judicial encroachment" on the medical practitioner's field of expertise:

Upon the concurrence of the guardian and the family of Karen, should the responsible attending physicians conclude that there is no reasonable possibility of Karen's ever emerging from her present comatose condition to a cognitive, sapient state and that the life-support apparatus... should be discontinued, they shall consult with the hospital's "Ethics Committee" or like body of the institution in which Karen is then hospitalized. If that consultative body agrees (with the prognosis) the life-support system may be withdrawn and said action shall be without any civil or criminal liability therefor on the part of any participant, whether guardian, physician, hospital or others.

This section of the judgment is, to say the least, problematic. At the time of the judgment such committees did not exist and the judgment offered only the most perfunctory guidelines as to their composition, mandate, function and scope of authority. Most radical, however, was the suggestion that such committees would be granted an immunity from prosecution and could exercise in effect a veto over the patient's or guardian's choice. Certainly this was attractive to hospitals. They would be free to operate without the necessity of invoking a time-consuming and expensive judicial machinery and still operate under an immunity from equally costly prosecution. But the judgment is of dubious authority for the proposition that all such committees could operate behind a cloak of immunity.

After *Quinlan* there was a rush to establish ethics committees, and a flood of literature analyzed their role and composition. Approval of the committees was far from unanimous however. In the *Saikewicz* decision, a Massachusetts court criticized the *Quinlan* judgement and asserted the court's primary decision-making role, apparently requiring judicial approval for all cases involving refusal of treatment:

We do not view the judicial resolution of this most difficult and awesome question — whether potentially life-prolonging treatment should be withheld from a person incapable of making his own decision — as constituting a "gratuitous encroachment" on the domain of medical expertise. Rather, such questions of life and death seem to us to require the process of detached but passionate investigation that forms the ideal on which the judicial branch of government was created.

The procedure recommended in *Saikewicz* was to require the institution of a complex guardianship procedure with full court hearings and representations by all interested parties. It explicitly ruled out the delegation of this supposedly judicial function to a *Quinlan*-type ethics committee:

We take a dim view of any attempt to shift the ultimate decision-making responsibility away from the duly established courts of proper jurisdiction to any committee, panel or group, ad hoc or permanent.

Clearly this decision is drafted in broad and often extravagant terms, and the reaction of the medical community and their legal advisors was

sharp. Unfortunately, the response was as extreme as the decision itself. *Saikewicz*, while excessive in scope, was interpreted in some quarters as imposing on hospital staff a requirement to continue treatment, however extraordinary its nature, until a court order permitted its discontinuance. Thus George Annas, in his article "Reconciling *Quinlan* and *Saikewicz*", records a case of a dying woman being defibrillated 70 times in a 24 hour period and an application for authorization to withdraw treatment from a brain dead individual in a state which had already adopted the Harvard test as a legal definition of death. Somewhat sardonically, the author pointed out that there should be no duty to treat a corpse.

More helpfully, Annas suggested that the *Quinlan* and *Saikewicz* judgments could be interpreted narrowly and reconciled on their facts. *Saikewicz* concerned a 67-year-old severely handicapped patient with leukemia and posed the question whether a course of painful radiation therapy could be withheld from him when it was suggested that the majority of competent patients would choose to accept the treatment. There was thus the necessity of choosing between two equally valid courses of treatment, and such a choice involved ethical and legal rather than purely medical considerations. Court approval for withholding treatment was therefore appropriate, as the judicial process permitted the competing interests to be canvassed in full. Where the patient's condition is hopeless, however, as in *Quinlan*, Annas would suggest that the state can never demonstrate an interest compelling enough to outweigh the patient's constitutional right as exercised by a guardian. The issue in these cases is more appropriately one of medical prognosis, and there is therefore less reason to require that the legal guardian seek court approval before exercising the incompetent patient's right to refuse treatment.

...in inquiring whether treatment may be withdrawn the focus should be on the "prognosis as to the reasonable possibility of a return to cognitive and sapient life"...

More recent decisions have given judicial effect to this point of view and have provided for what seems to be a logical and humane two-tiered approach to withdrawal of care decisions. *Re Coyer* rejected the amorphous "ethics committee" approach of *Quinlan* and noted that the proper focus of the initial inquiry in these cases is the likelihood of the patient's recovery to a cognitive, sapient state. The Court correctly asserted that this determination is uniquely medical in character. As such, it should be left to the attending physician. Still, safeguards must be provided even at this level, and the Court suggested that the necessary protection could be achieved by referring the case to a prognosis board make up of the attending physician and no fewer than two physicians with qualifica-

tions relevant to the patient's condition. Should there be disagreement among the physicians as to the prognosis, uncertainty among family members or the guardian as to the patient's wishes, or difficult choices like those in *Saikewicz*, an application to the court could be made to have the dispute resolved. This suggests that the court need not play a role in every substantive medical decision, but, where problems arise, a clear pattern

for *Saikewicz* reproduced above to the effect that decisions to withdraw treatment should not be delegated to a medical ethics committee, doctor, family members or a guardian. The quotations are curious because this was not a case which involved withholding treatment, but the references may be explained if it is seen that *Pinel* involved a choice between two ethically valid courses of treatment where extra-medical factors had to be considered. *Pinel* does not



of medical and judicial review is made available and can be invoked by any interested party.

These cases are all from the United States. In Quebec, the medical problems are identical, but the legal questions are different and the case law not as spectacular. Certainly Canadian courts have not gone as far as their American counterparts in either delimiting a constitutional right of privacy or imposing ethics committees on hospitals. Still the starting point is much the same. In Quebec the doctrine of patient autonomy is embodied in the notion of the inviolability of the human person as set out in the Civil Code, and in Quebec as in the United States, the patient's capacity to

therefore suggest that court approval is required in all cases of administering or withdrawing treatment, merely that the courts will not readily confer upon either doctors or an ethics committee the power to override a patient's decision. Nor should *Pinel* be seen as an outright rejection of ethics committees, which can fulfill a valuable function. Rather, the decision merely restricts the scope of their authority.

If *Pinel* is understood as asserting the limited right of a patient to refuse treatment, the question then becomes what mechanisms exist to protect this right. Certainly in medical emergencies the doctrine of implied consent provides physicians with the power to intervene surgically or otherwise to save a patient's life. But in non-emergency situations, as where an incompetent person is a long-term patient, it would seem that the incompetency of the patient does not give the medical team an unfettered

right to proceed as it feels appropriate. The legislature has provided several mechanisms designed to ensure that the patient's rights survive incompetency. First, the Civil Code provides for the judicial appointment of a curator who is vested with the power to consent to medical treatment. In this context it is important to note that family members as well as physicians can act out of self-interest, and the curatorship mechanism provides a process whereby their motives may be judicially screened.

Second, after an examination by a psychiatrist, a patient unable to manage his property can be placed under the protection of the public curator, who then has the power to provide consent to treatment. While

PULLING THE PLUG

cont'd from page 5

perhaps less cumbersome to invoke than the Civil Code provisions respecting curatorship, the effectiveness of this regime depends on the ability and willingness of the public curator to represent the patient's interests. To date it is far from clear that the public curator is willing to accept this responsibility fully.

Third, the courts may exercise its *parens patriae* power to authorize treatment without recourse to guardianship provisions or curatorship.

All of these mechanisms depend to some extent on the hospital administration or family to initiate the judicial process. The procedures are legally and administratively complex, create delays and may be seen as infringing upon the physician's traditional power of deciding what is in his patient's best interest. Despite these drawbacks, a curator should be appointed in non-emergency situations concerning incompetent patients, both to protect the notion of patient autonomy and to protect hospitals and physicians from potential legal action.

Once a curator is appointed, the courts need not be directly involved in all treatment decisions. The physician still remains primarily responsible for determining the patient's prognosis. Furthermore, the prognosis board recommended in *Coyler* is already present in many Quebec hospitals which, in internal regulations, provide for mandatory staff consultations in certain specified situations. Once the prognosis is confirmed and a recommended course of treatment presented to the guardian, the court's intervention would only be necessary in particularly difficult cases, or where there is an irreconcilable difference in opinion between either the guardian and physicians or the physicians themselves.

This procedure provides a means of protecting the incompetent patient's rights, but in the absence of reported cases, the limits of the physician's duty to treat remain unclear. No general principle has been formulated by the courts, but the Canadian Medical Association's *Code of Ethics* (1982) is instructive. Articles 18 and 19 provide that an ethical physician "will allow death to occur with dignity and comfort when death of the body appears inevitable" and "may support the body when clinical death of the brain has occurred, but need not prolong life by unusual or heroic means." These provisions are not comprehensive statements of the legal duties of physicians, but they suggest that, in Canada, the confusion between a definition of death and the obligation to treat has been avoided. In doing so, the *Code of Ethics* recalls a nineteenth-century poet's amendment to a much older ethical principle, one which might well provide a guideline to both legal and medical practitioners:

*Thou shalt not kill,
But needst not strive
officially to keep alive.*

Dr. Dawson Schultz: Clinical Ethicist

by Debra Raicek
Faculty of Law

Dr. Dawson Schultz represents a new breed of clinical ethicists in North America. His philosophy doctorate was followed by a post-doctoral fellowship in clinical ethics. His training has led him to Montréal, and he is now working at the Montréal Children's Hospital as an ethical advisor assigned to specific cases. At the Bio-Ethical Institute, he is a senior research scholar.

Clinical ethics is a profession that stretches across those contentious areas where medicine and ethics meet. Schultz is involved in a research project dealing with chronic illness in an attempt to merge principles developed by both philosophy and empirical research. At the Bio-Ethical Institute, he is also involved with workshops for hospital administrators, and training programs in clinical ethics for qualified professionals. His busy schedule is supplemented by ethics lectures to medical students.

The field of clinical ethics is new. In fact, it has come into being within the past decade. Today in North America there are about four hundred professionals working in the medical humanities. They include lawyers, artists, philosophers

and theologians. Their task is difficult: it requires the application of relatively abstract concepts to practical cases. Describing the role that clinical ethicists play, Schultz stresses that "clinical ethics almost never deal with recipe issues that make headlines." Instead, "my work is a very, very specific in areas where decisions have to be made but are complicated by value judgments.

Clinical ethicists assist physicians to evaluate a case from an ethical standpoint and to arrive at an optimal decision from the standpoint of the patient. Schultz explains that "physicians are concerned with ethics to the extent that they want to make a good decision for the patient. However, the onslaught of modern technology makes it difficult to make good decisions. Some attending physicians are more paternalistic than others, Schultz notes, but on the whole there is a trend towards involving the patients and their families in decision-making processes.

Clinical ethicists assist in acute case where speedy decisions are required, and in chronic cases dealing with long-term patient care. Schultz discusses the ethical problems of "coding" a patient. For ex-

ample, there are a number of methods used to resuscitate a heart patient: "if someone is very sick and goes into heart-stop, the treatment you pick depends on the total coding of the patient. The question is: is it worth it to pull out all the stops?"

In a sense, law, medicine and ethics are three angles of a single issue. Nevertheless there are situations where, for example, the law may require one course of action and ethics another. As an extreme example of this divergence, Schultz refers to the medical experiments conducted in Nazi Germany. In today's society, law and ethics conflict in situations where the law requires maintenance of a patient far beyond the point where ethics would have created a cut-off point. Schultz sees the distinction as one between prolonging life and prolonging death. A hospital may be legally bound to sustain a patient and the courts view this as a life prolonging measure. But the patient may see this as painfully prolonging death. The conflict is a sensitive one, because it deals with self determination — the right of individuals to make the most crucial decisions about their very existence.



Schultz believes that the legislatures and the courts run behind the times. "They don't determine beliefs, they follow them." Ethics and medicine can shape the legal future, according to Schultz. Commissions such as the President's Commission on Medical Ethics in the United States have helped to raise public consciousness, and "through the media, the interest of the population has grown and will spur people to push for changes in the institutional, legal and legislative arenas."

The law and medical science are two very powerful and imposing forces between which individuals are placed. In many cases, the decisions that must be made are not based solely in the medical or legal arena; rather, they are inherent in the beliefs of every individual regarding the determination of their own being. It is here that the role of the ethicist comes into play. Aiding both physicians and patients to come to the most beneficial decisions, clinical ethicists like Dr. Schultz help to inject a softening edge to what sometimes can be a most difficult process.

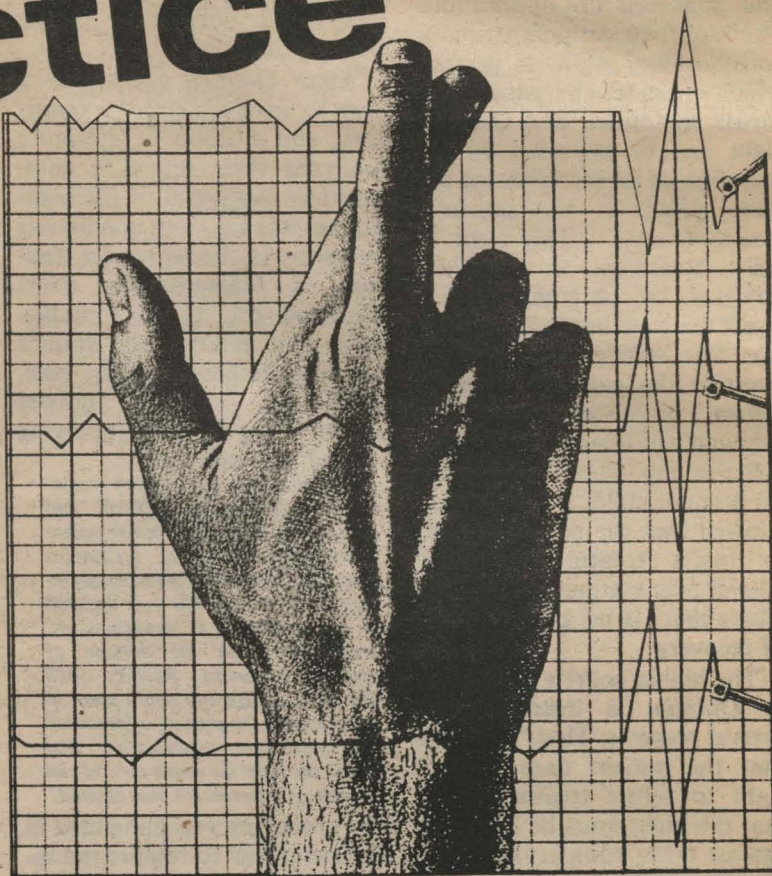
Malpractice

by Luc L. Oigny
Faculty of Medicine

Malpractice: this term is now part of everyday medical vocabulary. Fortunately, medical malpractice suits are far less common in Canada than they are in the United States. For example, American physicians can pay more than \$100,000 just for malpractice insurance as the epidemic of medicolegal suits are highly profitable both to patients and to their lawyers. Settlements are usually over \$50,000, and are sometimes in the six-digit range. Lawyers often keep one-quarter to one-third of the money on a contingent fee basis. Although illegal in parts of Canada, this fee schedule is allegedly used by some lawyers.

For Québec doctors, the malpractice-insurance premium is less than \$1,000, a figure not

alarming in itself. What is alarming, however, is the fact that it has increased three- to five-fold in the last five years, and rapid increases are expected in the near future. As a result, doctors will increase their fees in order to pay their higher insurance premiums. Under socialized medicine, taxpayers will end up paying the bill. Taxpayers must decide how they want their money spent. Unless they elect to pay higher taxes, they must choose between a status-quo in settlements and medical services, or increasing budget cuts which we are presently experiencing in the health system so as to allow for higher malpractice insurance fees. Alternatively, each patient could insure himself according to his needs

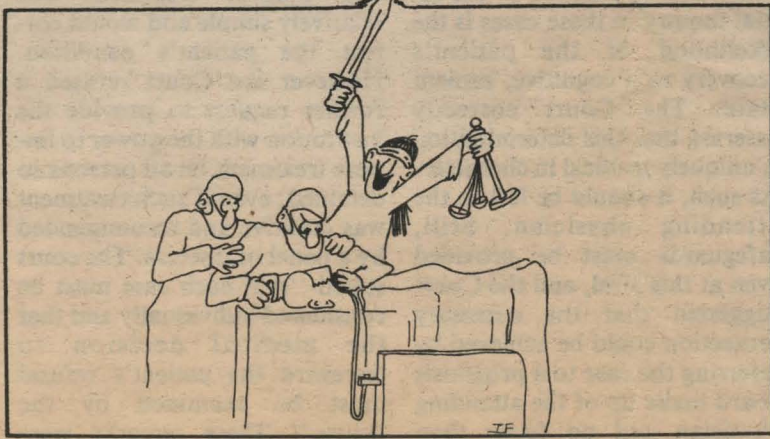


sure everybody.

If taxpayers decide to keep the cost of malpractice insurance under control, they must equate malpractice with negligence, and not with error. Special committees composed of laymen and physicians could be set up to study malpractice claims, in order to differentiate between error and negligence. If negligence is found, medical licenses should be suspended either temporarily or permanently; such sentences would be more equitable than merely

using taxpayer-money to settle claims. Naturally, only medical negligence would entitle patients or their family to financial settlements if they have been affected economically, or if their health has been severely impaired.

Negligence on the part of a physician is inadmissible; however, as a whole, doctors do their best to help their patients. Nevertheless, even doctors have erasers at the end of their pencils: to err is human, and doctors are human...





Artificial Insemination— Some Issues to Consider

by Ann Crawford
Faculty of Law

Artificial insemination (AI) services are potentially available to all women in Canada. In Quebec alone, as of 1983, four thousand children were born who had been conceived through the process of artificial insemination. AI is performed almost exclusively by physicians in clinics associated with university hospitals where the cost of the service is covered by provincial public health insurance schemes. However, the procedure of AI is a simple one and can be carried out with virtually no training.

The husband's sperm is used for the insemination if the recipient is married and the husband is fertile, otherwise donor sperm is used. Sperm donors usually receive twenty to fifty dollars, paid by the recipient and not covered by public health insurance schemes. Donors are primarily medical students. "Screening" of donor and recipient and "matching" of donor to recipient is carried out by the physician. Some physicians keep records which "link" donor and recipient.

Law students reading this brief description of the current state of the practice of artificial insemination in Canada, will likely have identified a number of problematic issues. The newspapers repeatedly print demands from doctors, lawyers, appointed commissions, and interest groups for legislation to resolve these issues. The purpose of this article is simply to raise a few of the difficult questions which must be dealt with in determining the nature, and at times, the appropriateness, of such a legislative response.

AI and fitness standards

Conception through artificial insemination forces us to address and question our traditional notions of parenthood. The concept of parents raising a child who is not their offspring is not a new one. We are all familiar with adoption. Adoption has also familiarized us with the process of erecting standards of fitness which must

be met before one can become a parent. Most would regard the existence of such standards as entirely reasonable. Indeed, we might agree that the state has an *obligation* to intervene to protect the welfare of an existing child.

Artificial insemination introduces new elements into the familiar scene. Take, as an example, the case of the infertile married couple. In order to reproduce through artificial insemination, such a couple must satisfy the criteria of access imposed by the individual physician who will perform the insemination. Generally, most physicians require the couple be physically, genetically, emotionally and otherwise "fit" to parent.

Are standards of suitability desirable in the area of birth technology? Fitness to parent is obviously not demanded of the couple capable of conceiving naturally. Yet, as noted above, we do require that certain standards of fitness be met before a couple may adopt a child. Does the fact that the mother (and sometimes the father) of a child conceived through AI, is the "biological" parent of that child render the process "closer" to natural parenting, and hence, alter our conviction that interference is reasonable? Perhaps the eugenic implications of limiting access to birth technology to those judged "fit", make us less comfortable with the imposition of fitness standards. Or does the possibility of protecting potential children from foreseeable harm — the stated goal of fitness standards — outweigh all other considerations. How do we identify harm in these circumstances when the alternative to the potential child is non-existence? Finally, if standards are thought necessary, we can seriously question whether the responsibility for judging "non-medical" fitness ought to rest with the physician.

Access to artificial insemination may be precluded by fac-

tors other than lack of genetic, physical, or emotional fitness. For example, single and lesbian women represent classes for whom access to birth technology is limited. Some physicians view artificial insemination as having a purely therapeutic function — that of treating infertility in couples — and thus will only inseminate married women. Psychiatrist Dr. Ron Bull explains: "(the) lack of a husband is a social problem, not a medical one." Other physicians may hold different, perhaps more personal reasons for restricting access to AI to unmarried women. Legislation could prevent this subjective and ad hoc determination of who should receive AI services. Currently, however, there is little agreement as to the position such legislation should take. The issue is again one of foreseeable harm to the potential child. With hospital-administered AI, the state has the means and, it is argued, the obligation to take steps to ensure the health and safety of the resulting children. However, the issue of whether children from single parent or homosexual parent families suffer some form of trauma in today's society is particularly sensitive. This may explain the lack of a legislative response to date.

Sperm donors

The process of recruiting and choosing sperm donors is also currently unregulated. The practice of a Montreal physician who carries on a large artificial insemination practice, is to advertise for and choose donors from within Quebec medical faculties. Some student donors are undoubtedly motivated by the payment offered for each donation. One medical student confided that he paid much of his way through school by making sperm donations. One might first question is whether a financial incentive to donate is appropriate, particularly given the current practice of recruiting students who generally have an immediate need for money. More importantly, as more

children are conceived through artificial insemination, the eugenic effects of using only one class of sperm donor should be considered. Legislation could expand the pool of potential donors, but should the law also take the role of prohibiting sperm bank services which, for example, provide sperm exclusively from Nobel prize winners?

Confidentiality

Legislation, it is said, is needed to ensure the confidentiality of the identity of the sperm donor. The current procedure of the physician mentioned above, is to keep medical records in such a way that the identity of the donor cannot be "linked" with that of the recipient. This practice is generally said to be in the best interests of all the participants. Furthermore, donor and recipient consent to this absolute confidentiality. However, one participant has not consented to such

Such a situation has not yet been faced by a Canadian court. One reason for this may be that children conceived through artificial insemination are generally not told the facts of their origin. Their birth records will reveal only the names of the recipient parents as it is the practice of most physicians to refer a recipient of artificial insemination to an obstetrician who is unaware of the circumstances of conception. If the issue is to be dealt with by legislation, the competing interests of access to one's genetic heritage, and confidentiality of the donor will have to be addressed.

Finally, it should be mentioned that the federal government is reportedly considering legislative controls to regulate such matters as sperm storage and screening of sperm for genetic or infectious disease. Ethical questions are said to be "out of the department's mandate". However, it should be

Generally, most physicians require the couple be physically, genetically, emotionally and otherwise "fit" to parent.

secrecy — the resulting child. If the example of adoption is any indication, children are anxious to discover the identity of their biological parents, and Quebec courts have recently shown themselves more willing to provide them with the means to do so. But even a judicial order cannot produce the identity of a biological father where medical records make such a determination impossible.

pointed out that the imposition of legislative *controls* involves an implicit ethical decision that AI is an acceptable form of reproduction. Furthermore, by failing to consider "ethical questions" at this time, the government has at least seen it ethically fit to allow artificial insemination to continue to be practised subject only to controls imposed by the individual physician.

Product Liability in the Medical Field On the Frontier

by Pearl Eliadis
Faculty of Law

The business of medicine is big business. The pharmaceutical industry is the third largest in the world. It is ironic that an industry geared to healing and the alleviation of pain can engender extraordinary suffering. Corporate irresponsibility in the development and marketing of medical products has become an important legal and medical phenomenon of this century. As huge corporations battle for dollars and market shares, haste and carelessness have often spawned multi-million dollar law suits and have left human wreckage in their wake.

The hybrid of business and medicine will always be a monster unless care and judgement are consistently exercised. The issues do not only involve traditional "business" decisions. The sheer magnitude of these operations necessarily draws upon medical and legal resources in order to ensure financial survival. Medical and legal professionals employed by these multinational leviathans are implicated in the destruction

inflammatory disease resulting in infertility, major surgery and, in approximately fifteen cases, death.

The Dalkon Shield was developed in the sixties. A.H. Robins Company purchased the device from its inventors and modified the product. The changes were not tested. When the Shield was introduced the company used the original test results of the unmodified product in order to market it. Among the most important changes was the decision to make the plastic membrane of the Shield substantially thinner. As a result, when physicians attempted to discover the cause of complaint from women wearing the Shield, they were unable to see the radio opaque I.U.D. in x-rays. Another dangerous feature of the device was its serrated edges, designed to prevent expulsion of the device. They also caused its migration to the upper portions of the uterus and perforation of the uterine wall. Once perforation occurred, the braided string attached to the Shield acted as a breeding ground for dangerous infection resulting in pain, bleeding and

The misdeeds of A.H. Robins far exceeded the bounds of mere recklessness. The company manipulated every procedural mechanism in the battery of dilatory techniques available to their expert legion of attorneys. Company employees were forbidden to give testimony on the grounds that intracorporate communications related to the development and analysis of the Shield was mere "hearsay". Physicians were given misleading information about the safety of the Shield: at least one Montreal woman was informed by her physician that the Dalkon Shield was the safest and most reliable product of its kind on the market.

It is not surprising that the ensuing litigation absorbed extraordinary amounts of time, legal and medical expertise. In ten years of caselaw, only a fraction of the estimated 2.7 million women who have worn the Shield have had the initiative and legal means to pursue the company. To date, approximately 224 million dollars have been paid out by A.H. Robins to its victims. It is only recently that the company has launched an unprecedented media campaign recalling the Shield and warning women of its dangers. Undoubtedly, these belated measures have been triggered by an expensive litigation.

Medicine is supposed to be a helping profession. Although law is not as readily associated with that label, it is supposed to be one as well. The integrity of both professions is shrouded in the shadow of a shrug of corporate shoulders. Nowhere was this clearer than in the speech by Judge Miles Lord of the Federal District Court, following his judgment against the A.H. Robins Company. The following extracts from his speech were directed to the senior officials of that company.

Today as you sit here attempting once more to ex-

tricate yourselves from the legal consequences of your acts, none of you has faced up to the fact that more than 9,000 women claim they gave up part of their womanhood so that your company might prosper. I dread to think what would have been the consequences if your victims had been men rather than women — women, who seem through some quirk of our society's mores, to be expected to suffer pain, shame, and humiliation.

If one poor young man were, without authority or consent, to inflict such damage upon one woman, he would be jailed for the rest of his life. Yet... when the time came for these women to make their claims against your company, you attacked their characters. You inquired into their sexual practices and into the identity of their sex partners. You ruined families and reputations and careers in order to intimidate those who would raise their voices against you.

Mr. Robins, Mr. Forrest, Dr. Lunsford: Under your direction, your company has continued to allow women, tens of thousands of them, to wear this device — a deadly depth charge in their wombs. The only conceivable reasons

that you have not recalled this product are that it would hurt your balance sheet and alert women who have already been harmed that you may be liable for their injuries. You have taken the bottom line as your guiding beacon and the low road as your route. That is corporate irresponsibility at its meanest. Confession is good for the soul, gentlemen. Face up to your misdeeds. Rectify this evil situation.

If this court had the authority, I would order your company to make an effort to locate each and every woman who still wears this device and recall your product. But this court does not. I must therefore resort to moral persuasion and a personal appeal to each of you. Mr. Robins, Mr. Forrest, and Dr. Lunsford: You are the people with the power to recall. You are the corporate conscience.

Please, in the name of humanity, lift your eyes above the bottom line. You, the men in charge, must surely have hearts and souls and consciences.

Please, gentlemen, give consideration to tracing down the victims and sparing them the agony that will surely be theirs.



from "Paintings on Paper" by Su Schnee

An Important Health Warning To Women Using An IUD

If you are still using an intra-uterine birth control device (IUD) inserted in the early to mid 1970s, this message is for you. Many women had an IUD called the Dalkon Shield inserted during that time. It is important that each Dalkon Shield be removed, since there is substantial medical opinion that its continued use may pose a serious personal health hazard. If you are still using a Dalkon Shield, A. H. Robins Company will pay your doctor or clinic to remove it. A. H. Robins ceased distribution of the Dalkon Shield in 1974. Many claims have been made that the device causes health problems, including pelvic infections, that may result in serious injury or death. In 1980, A. H. Robins advised doctors to remove the Dalkon Shield from any woman still using it. In 1983, the U.S. Food and Drug Administration and other



The Dalkon Shield

government agencies issued the same advice based on their concern about pelvic infections among Dalkon Shield users.

A. H. Robins will pay your doctor or clinic for any examination needed to find out if you are using the Dalkon Shield. If you are, A. H. Robins will pay the cost of having it removed.

WHAT TO DO

If you know you are using a Dalkon Shield IUD, or if you are using an IUD inserted in the early to mid 1970s and are unsure of the kind, call your doctor or health clinic for an appointment. Your call will be in confidence, and there will be no cost to you.

If you have further questions, please call A. H. Robins Company toll free. The number is 1-800-247-7220. (In Virginia call collect 804-257-2015.)

A-H-ROBINS

1407 Cummings Drive, Richmond, Virginia 23220

Recent Advertisement by A.H. Robbins Co.

wrecked by corporate irresponsibility.

Thalidomide and DES are among the better-known products which sparked the debate about the state of corporate consciousness. Another is the Dalkon Shield, an intrauterine device manufactured by the giant American company, A.H. Robins of Richmond, Virginia. To date there have been over 10,000 claims against that company for the disastrous effects of the Shield. The Dalkon Shield has been responsible for tens of thousands of women who have suffered from pelvic

permanent disability in some women.

On a preponderance of evidence, courts have held that the company had been aware of the dangers inherent in its product. Nevertheless, A.H. Robins continued to market it until 1974, and did not bother issuing warning letters to physicians until 1980. One Federal District Court in Minneapolis granted a stunning 4.6 million dollar judgment against the company for marketing a product dubbed as an instrument of "death, of mutilation, of disease."

FRONTIER

cont'd from page 3

billion a year is spent on treating the problem after the fact, and only \$200 million a year is spent on preventative facilities.

A major difficulty in understanding the scope of the child abuse problem, according to Cohn, is that the commonly quoted figure of more than one million cases per year in the United States is an underestimate. The number of deaths per year is probably well in excess of — perhaps four

times — the 2,000 mark verified in reports by coroners and protective service agencies.

In Canada there is little doubt that child abuse and neglect is a growing problem. However, a national profile of Canadian statistics is not available because individual provinces tabulate these statistics and the data is not subsequently standardized to provide a national picture.

The National Clearinghouse on Family Violence has recently been established by Health and

Welfare Canada. This organization will provide consultation, information and assistance to professionals and governments.

Margaret Ann Smith, director of the social services department at the Montreal Children's Hospital, said that the fight to end child abuse has progressed from diagnosis and treatment to strategies for prevention. As chairperson of the Congress, she stated that more answers will come from within the community as a whole and not only from the Federal Government.